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14. ABSTRACT This study is a follow up to two projects, funded by the Office of Naval Research, which demonstrated that Virtual Reality Exposure Therapy was safe and effective for the treatment of Post Traumatic Stress Disorder in Service Members who served in Iraq or Afghanistan, and that it worked better than treatment as usual. In this study, we are attempting to discover if the Virtual Realty is actually the active component of the treatment. Participants with PTSD are randomized to receive the same treatment that was successful in the previous projects, or the same treatment in which a simple, still computer image replaces the Virtual Reality. Progress on the grant was initially delayed pending secondary review from the Department of the Navy, and approval to recruit from TATRC. During the intervening period, we performed clinical cases using the VR to train therapists, registered the project with clinicaltrials.gov, upgrade our software, and establishing recruiting pools. Several volunteer therapists and technicians were recruited to assist the project. We received approval in September 2009, and are now running with 8 patients enrolled in the first 10 week block of treatment. We have also gone through annual review for our IRB, and have been approved for our second year. We anticipate our post treatment assessments being completed in early November 2009.					
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INTRODUCTION:

Exposure Therapy (ET) is the current gold standard for treating Post Traumatic Stress Disorder (PTSD). Although ET has the best evidence in its favor, it is also clear that the treatment is less than perfect in achieving remission of PTSD. Attempts have been made to improve on traditional ET by augmenting the exposure using Virtual Reality (VR). Trials of VR assisted ET (VRET) showed this method to be safe and effective, and suggested remission rates that were higher than normally seen with ET alone. For the treatment of phobias, head to head comparison with traditional ET has shown VRET to be superior. For PTSD, trials that directly pit VRET against traditional ET, and against other traditional therapy, are ongoing, but it is already clear that some individuals who fail to respond to traditional ET do get better once VR is added. Lost in the rush to develop VRET, however, has been any direct testing of its signature aspect, the VR itself. There are theoretical reasons to believe that VR might enhance ET in special ways. However there are other reasons to believe that any form of Cued Exposure Therapy (CET) that introduced sights and sounds from the trauma would do just as well. VR, although exciting, is expensive, cumbersome, and not available at most treatment facilities. If similar effects could be achieved using more primitive technology, it would open up the possibility of enhanced ET to a much wider range of patients. Conversely, if VRET were shown to be superior to simplified CET, it would argue for a unique role of VR in psychotherapy. Not only would this be theoretically important for neuroscientists, it would indicate VRET as a “platinum” standard for treating PTSD. For the past four years, programs at Naval Medical Center San Diego (NMCS D) and Naval Hospital Camp Pendleton have collaborated with VR companies and researcher to build and test VR systems to treat PTSD in Service Members returning from Iraq and Afghanistan. NMCS D thus has the experience to perform the necessary experiments. The existing equipment also means that NMCS D has the unique ability to carry out such a test without any additional input from the companies that make VR systems. We set out to perform a randomized, head-to-head study that compares VRET to CET. The same techniques, measures, and controls would be used that NMCS D has already put in place to develop VRET for PTSD. Also, a cost-benefit analysis would be used to determine the benefits of VRET.

BODY: The original statement of work outlined one major task to be accomplished or started in the first year of this project.

Task 1 -- Month 1 to month 6: Recruitment and hiring of research personnel and obtaining IRB approval to work with human subjects at NMCS.

This task has been completed. Initial, local IRB approval was obtained in October 2008, within one month of the project starting. Two therapists and a research technician were hired. The therapists received training in Prolonged Exposure Therapy, and supplemental training in Virtual Reality therapy. They also completed full clinical credentialing at Naval Medical Center San Diego, and Camp Pendleton. Each therapist completed several training cases in Virtual Reality Exposure Therapy, with cases reviewed under the supervision of the Primary Investigator. This also served as a practice for assessing protocol validity, and for practicing assessment methods by research technicians. In addition to the research technician hired via the grant, two additional technicians have volunteered for the project, and have been added through IRB channels as official investigators on the grant. Our technicians provided detailed assessment services for Naval Medical Center San Diego PTSD programs. By doing so, they not only provided a valuable clinical service to the DoD, but enhanced their training, and achieved a 94% inter-rater reliability on the CAPS. Providing useful clinical services while waiting to be allowed to formally enroll participants in the study helped establish a steady referral stream and establish the credibility of the program. As a service to military mental health, a training was also held to train other therapists who might want to use VRET clinically. Twenty four therapists from military facilities received training in VRET. Four of these have volunteered to serve as additional research therapists and investigators on the project, without additional cost to the grant.

We did experience an unforeseen delay in resolving conflicts between Department of the Navy and Department of the Army policies on project approval. As a result, we did not receive permission to recruit from TATRC until September of 2008, a six month delay from our initially anticipated timeline. This issue has now been resolved, however. We have come up for annual IRB review at Naval Medical Center San Diego, and passed without difficulty.

Task 2: Month 7 to month 42: Recruit and enroll approximately 8 patients a month, with the expectation that 4 of these will enter VRET or CET treatment phases, and be eligible for intention to treat analysis

We started this phase six months late. However, we are initially meeting recruiting goals. Ten volunteers were assessed. Eight of these were eligible for treatment, and entered VRET or CET treatment in October 2009. One of these participants has had an interruption of treatment due to an outbreak of the swine flue. However, the others are progressing in treatment. We will have our first post-treatment assessments in early November 2009.

KEY RESEARCH ACCOMPLISHMENTS:

- 1) IRB approval and 2nd level approval received. IRB annual renewal complete.
- 2) Six research therapists have been trained in VRET therapy (two of them directly funded by the grant). Five of these have completed training cases, and had their cases monitored for protocol adherence.
- 3) Protocol Adherence method in place.
- 4) All research measures, including physiological measures and clinician administered tests, have been put in place and observed for reliability. >94% agreement on clinician administered tests.
- 5) Ten subjects consented for participation, and eight of these met inclusion criteria, were randomized, and are engaged in VRET or CET.

REPORTABLE OUTCOMES: No post-treatments have been completed. The first post-treatment assessments are anticipated in November 2008.

CONCLUSION: Participants have engaged in VRET and CET without adverse consequences related to either version of the therapy. No post treatment results are yet available.

REFERENCES: Not applicable.

APPENDICES: Not applicable.

SUPPORTING DATA: Not applicable.